IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RYMED TECHNOLOGIES, INC. AND DENISE MACKLIN, PLAINTIFFS, V. ICU MEDICAL, INC., DEFENDANT	Civil Action No. 3:10-cv-01067 TJC Chief Judge Todd J. Campbell Magistrate Judge Bryant **JURY DEMAND**
ICU MEDICAL, INC., COUNTERCLAIMANT, V. RYMED TECHNOLOGIES, INC., COUNTERDEFENDANT.	

JOINT STATEMENT RE: PROTECTIVE ORDER

Pursuant to Local Rule 37.01(a) of the United States District Court for the Middle District of Tennessee, the parties, by and through counsel, notify the Court that a discovery dispute exists. Specifically, ICU Medical, Inc. ("ICU") has proposed a protective order in this action. RyMed Technologies, Inc. ("RyMed") and Denise Macklin ("Macklin") object to several provisions of the proposed protective order, including, but not limited to, whether or not the parties may designate highly sensitive information as "Attorneys Eyes Only," and, if so, the manner in which that should be accomplished.

The parties further state that they have conferred in good faith in order to resolve this dispute as required by LR 37.01(b)(3) and Fed. R. Civ. P. 26(d) but have been unable to reach agreement. The parties raised the possibility of a dispute involving the proposed protective order with Magistrate Judge Bryant at the Initial Case Management Conference. Pursuant to Magistrate Judge Bryant's suggestion, the parties are now submitting this dispute to the Court for resolution by providing this Joint Statement.

For the Court's convenience, a copy of the proposed protective order, with the disputed provisions highlighted, is attached as Exhibit A. A copy of ICU's proposed protective order is attached as Exhibit B. A copy of RyMed's proposed protective order is attached as Exhibit C.

I. STATEMENT OF FACTS

A. ICU'S STATEMENT OF FACTS

This is the third action between ICU and RyMed. On July 27, 2007, ICU initiated a patent infringement action against RyMed in the District of Delaware (the "Delaware Action"). RyMed responded by, among other things, filing an action less than three months later against ICU in the Central District of California alleging trademark violations and unfair competition (the "California Action"). After granting summary judgment on all of RyMed's claims in the California Action, Judge Phaelzer invalidated the RyMed trademarks upon which the action had been based and entered judgment in favor of ICU. More recently, a jury in the Delaware Action unanimously found RyMed's InVision-Plus product (the subject of this lawsuit) to infringe on two of ICU's patents.

In each of the two prior actions, ICU and RyMed entered into stipulated protective orders on terms substantially identical to those in dispute in this action.[1] These terms are especially warranted in this case for the following reasons:

- "ICU and RyMed are competitors in the development and marketing of needleless IV connectors" (RyMed's First Amended Complaint, ¶ 23);
- "RyMed and ICU have a long and contentious history as competitors" (RyMed's First Amended Complaint, ¶ 4);

[1] RyMed's re-characterization of these facts to "we've always done it this way," ignores that the prior protective orders were entered upon the advice of two well respected law firms, were ordered by two federal district courts, were not later sought to be modified in any particular at issue here, and were, as intended, self executing and did not require court intervention or supervision.

- RyMed is a significantly smaller company with fewer resources than ICU[2] so stands to benefit immeasurably by obtaining ICU's trade secret design, marketing, and sales information;
- RyMed has already been found by a jury to have infringed ICU's patents; and,
- RyMed has already demonstrated a willingness to bring meritless claims against ICU for strategic reasons.

In the proposed protective order, ICU seeks to obtain the identical protections previously agreed to between ICU and RyMed, including: (A) the ability for all parties to designate information as attorneys eyes only ("AEO"); (B) a limitation on the number of recipient party's employees who would be allowed view non-AEO designated confidential information; (C) the ability of the producing party to object prior to its confidential or AEO information being provided to a paid consultant; (D) the prohibition of persons privy to trade secret design information from prosecuting patents in the field for two years; (E) the requirement that the producing party be promptly informed of breaches of the protective order so it may take such protective actions as are necessary; and (F) a requirement that the other sides' confidential and AEO documents be destroyed or returned at the end of this action. Wagner Decl. ¶ 4.

These provisions are justified in this action between two direct competitors in a quickly evolving and technology-driven market. Needle-free IV connectors are generally grouped into three categories: "Negative Displacement" connectors (upon disconnection of the syringe from the connector, blood or other fluids are drawn up into the catheter, toward the connector and away from the patient); "Positive Displacement" connectors (upon disconnection of the syringe from the connector, blood or other fluids are pushed out of the connector toward the catheter end

[2] RyMed alleges in its complaint that "ICU is a publically-traded company with approximately $220 million in annual sales. Plaintiff RyMed is a privately-held company with annual sales of approximately $7 million." First Amended Complaint, ¶ 3.

and the patient); and, "Neutral Displacement" connectors (which exhibit minimal movement of fluid in either direction upon disconnection). RyMed's InVision-Plus, ICU's MicroCLAVE®, and Vygon's Bionector are the only Neutral Displacement Connectors on the market.[3]

Not surprisingly, then, RyMed targets ICU in its marketing efforts. For example, RyMed's website prominently features an "IV Connector Virtual Tour." After its own device, the first two competing devices RyMed "tours" on its website are ICU's MicroCLAVE® and CLAVE®. *See* screenshot of RyMed's "IV Connector Virtual Tour." Wagner Decl. ¶ 10 and Exh. I. Vygon, in comparison, has a very small U.S. market presence and is not even mentioned on the RyMed "IV Connector Virtual Tour."

RyMed's success and continued existence, therefore, depends upon its ability to convince hospitals that its neutral displacement connector is superior to ICU's. If RyMed's key personnel were allowed access to ICU's confidential sales, marketing, and design information RyMed would gain a significant but unfair competitive advantage. For example, RyMed could launch pre-emptive marketing campaigns to counter ICU's future marketing plans and competitive strategies. Similarly, RyMed could use ICU's sales leads and potential customer information to target customers where ICU was making head-way. Further, technology companies such as ICU as well as RyMed expend significant resources to keep product development plans secret until the new or revised product is ready to launch; allowing RyMed employees access to such information would allow RyMed access to information no other competitor has and no competitor should have. "[T]he undisputed fact that [the parties] are direct competitors in the same industry provides a presumption that requiring [one party] to disclose [sensitive and

[3] See ECRI Institute, "Needleless Connectors Evaluation," *Health Devices*, Vol. 37, No. 9, Sept. 2008 at 268 and Hadaway L and Richardson D, "Needleless Connectors: A Primer on Terminology," *Journal of Infusion Nursing*, Vol. 33, No. 1, January/February 2010. Wagner Decl. ¶ 10 and Exhs. G and H.

confidential commercial] information to [the other] would be harmful." *International Coal Group, Inc. v. Tetra Financial Group, LLC*, 2010 WL 2079675, 2 (D.Utah,2010).[4]

Further, if RyMed's personnel were privy to ICU's trade secret design information, RyMed could use that information to attempt to design around or otherwise knock off ICU's patents, as they have done in the past. The patent verdict in the Delaware Action establishes that RyMed, and it's President, Dana Ryan, are willing and capable of improperly using, or knocking off, ICU's information for their own ends. Consequently, neither Mr. Ryan nor any other RyMed employee should be allowed access to additional ICU confidential information merely because RyMed has chosen to file another meritless action against ICU.

RyMed has claimed that its principals need access to ICU's trade secrets in order to prosecute this case. Both parties, however, were able to prosecute and defend the Delaware Action and California Action with the same protective order provisions in place. RyMed further claims it will be a hardship to retain experts to assist in the evaluation of ICU's documents. However, both parties were able to, and in fact did, retain technical expert witnesses to testify in the prior actions, which experts are already familiar with both parties' devices and therefore are already well prepared to assist counsel in this action. With respect to sales and marketing information, there is no reason why RyMed's counsel, a law firm with extensive experience in commercial litigation, should be incapable of evaluating and analyzing such materials.[5]

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[4] Other examples of sensitive and confidential commercial information that would harm ICU if known to a competitor include: current sales volumes to particular institutions, information concerning pricing and profits, ICU's supply sources and availability, customer feedback regarding either ICU's or RyMed's products, sales-call notes, product development and modification designs and plans, and product testing results particularly with respect to new products under development or modifications of current products,

[5] "In response to the plaintiff's contention that it must have access to the defendant's pricing and profit information so that it may discuss settlement or damages with its counsel, this kind of information often has been determined to be "highly confidential-attorneys' eyes only"

Finally, RyMed's claim that the AEO designation was abused in the prior actions to *RyMed's detriment* is simply false. In the California Action, it was RyMed that produced virtually every document in its possession, including telephone books, personal correspondence, expense reports and duplicate copies, amounting to nearly 200,000 pages and marked the vast majority of those documents "Highly Confidential," the designation for AEO documents.[6] Finally, in the event that a party does over-designate its documents, the proposed protective order provides a mechanism to remedy any such abuse through an application to this court.[7]

Where, as here: (1) millions of dollars of research and development, and potential sales, are at stake; (2) the parties are essentially the only players in a two-competitor market; and, (3) one party has a history of filing meritless actions for strategic purposes and of making improper use of the other's intellectual property, the proposed protective order is not only justified, but necessary to protect ICU from the substantial risk that RyMed will use ICU's sensitive and confidential information in a manner that causes ICU significant harm.

B. RYMED AND MACKLIN'S STATEMENT OF FACTS

RyMed disputes many of the "facts" as set out above by ICU. Rather than going into a

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material in similar intellectual property cases." *Inter-Med Inc. v. ASI Medical Inc.*, 2010 WL 2679992, 2 (E.D.Wis., 2010).

[6] Wagner Decl. ¶ 5. Below, RyMed speculates whether documents produced in the prior cases and designated AEO overlap with documents that would be produced in the instant case. Not only does RyMed's counsel lack any basis for such assertions, but the point is irrelevant. If a document produced in *this* case is appropriately designated as "AEO," it should in fact be treated as AEO. If it is designated AEO in this case but that designation is not warranted, the designation can be challenged.

[7] While RyMed is correct that ICU never sought court assistance with respect to RyMed's over-use of the AEO designation, ICU did raise the issue informally with RyMed's counsel. Wagner Decl., ¶ 10 and Exh. N. The fact that such issues could be worked out without court intervention weighs in favor of issuing the protective order requested by ICU.

lengthy argument about the relative merits of this case or prior cases[8] (which is essentially what ICU has done), RyMed will simply provide the Court with an overview of the claims and defenses at issue in this case as they pertain to the need for a protective order.

On or about November 3, 2010, counsel for ICU sent a demand letter to RyMed's patent counsel. In it, ICU accused RyMed of wrongful conduct concerning the marketing of RyMed's InVision-Plus® connector and ICU's Clave® and MicroClave® connectors. Faced with ICU's unfounded allegations that ICU's comparative advertising constitutes "false advertising and misbranding in violation of federal and state laws . . ." and its threat to "take action against RyMed," RyMed filed the present suit seeking a declaration that its conduct was not wrongful or unlawful.[9] RyMed also pointed to false statements by ICU. ICU has answered and counterclaimed, asserting Lanham Act claims.

While RyMed readily admits that it and ICU are competitors with a history of litigation, that alone is not enough to justify the Protective Order being proposed by ICU. Simply put, the "we've always done it this way" argument is unpersuasive, particularly when one looks at the scope of discovery in this matter. Pursuant to Rule 26 of the Federal Rules of Civil Procedure, the "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any

[8] In particular, ICU selectively characterizes patent litigation pending in Delaware. Although the Jury in the Delaware Litigation found in ICU's favor on two counts of patent infringement (2nd and 3rd Patents), the Jury also found (1) no infringement by RyMed of the 1st Patent; (2) no literal infringement of any independent claim of the 2nd patent; and, (3) no willful infringement of any of the three patents. More importantly, however, the Delaware Action is ongoing with post-trial motions yet to be resolved, and with both sides requesting a new trial due to the inconsistent jury verdict. Finally, the Delaware Court will hold a hearing at the a later date to determine whether the jury verdict can stand. The present state of the Delaware litigation – which ICU does not seem to challenge – belies ICU's hyperbolic and baseless claim that "RyMed [has a] history of knocking off ICU's products and bringing frivolous claims."

[9] Given its threat of litigation and its counterclaims which are consistent therewith, it is not surprising that ICU proposed in the ICMO that it be treated as the plaintiff in this litigation. Nevertheless, in its statement below, ICU points to the fact that "RyMed chose to bring this action" as justification for the over burdensome Protective Order it is seeking to have entered.

party's claims or defense." In this Lanham Act case, the claims and defenses of the parties center around whether either party has made false or misleading statements about its product or the other's product. Given these claims (and the available defenses), discovery largely should revolve around what each side said (both verbally and in writing) and what support if any they had for saying it. This likely would include marketing materials already shared with customers and potential customers,[10] communications with customers and potential customers regarding the products at issue, research or other testing which bears on the claims made by both sides, published articles, product samples and the like.

To that end, below is what ICU disclosed in its Rule 26 Disclosures as the as the categories of documents ICU may use to "support its claims or defenses":

- Physical samples of the MicroCLAVE® and CLAVE® connectors;
- Physical samples of the InVision-Plus;
- Marketing materials relating to the MicroCLAVE® and CLAVE® connectors;
- The "Comparative Matrix," Exhibit 4 to the First Amended Complaint;
- RyMed's marketing materials, including web-based documents, brochures, fliers, and posters;
- RyMed's labeling documents;

[10] ICU claims that it should not have to produce "[secret] product development plans . . . until the new or revised product is ready to launch." RyMed agrees, and expects the same for its yet to be disclosed marketing materials. Unless either side is relying upon those plans to support statements they have already made or to challenge statements the other side has made, these plans appear to be beyond the scope of permissible discovery.

- Documents submitted to the FDA by RyMed;
- Documents submitted to the U.S. Patent and Trademark Office by RyMed;
- Needle-free Connector Presentation[1] documents, including Power Point presentations, notes, and audio and/or video recordings;
- Documents analyzing or studying the CLAVE® or MicroCLAVE®, including, without limitation, articles, publications, test results and clinical studies;
- Documents analyzing or studying the InVision-Plus, including, without limitation, articles, publications, test results and clinical studies; and
- Industry publications and studies regarding or referring to the InVision-Plus, the CLAVE® or the MicroCLAVE®.

It is hard to imagine how any of the above documents could be considered "highly sensitive" such that they should not be kept from the client representatives in this case.[11]

When the proper scope of discovery is considered, the likelihood that "highly sensitive" material will be exchanged is greatly reduced.[12] Put another way, if one side has support for what it has said, then why would it not tell the other side what that support is? Presumably, each side readily communicates this information to its customers or potential customers (who have no

[11] ICU characterizes RyMed's legitimate concerns about the burdensome nature of its proposed Protective Order as a "parade of unfounded horribles." Setting aside such exaggerated rhetoric, the reality is that ICU has conceded that most of the documents and information at issue in this litigation are not AEO material. Rather, ICU strains to come up with information it presumably hopes RyMed will request in discovery that might be entitled to AEO coverage. To date, RyMed has not served any discovery requests so ICU's "the sky might fall" argument is premature at best. Given this reality, the compromise offered by RyMed – and rejected by ICU – that the Court be in a position to evaluate an AEO designation *when and if* called upon to do so comports with common sense and logic.

[12] It is also important to note that in the course of the trial in the Delaware Litigation, both sides were exposed to many of the documents previously designated AEO. Presumably, these are many of the same documents ICU would now like to designate as AEO in this action. Because the undersigned did not represent RyMed in the Delaware Litigation (or the California Litigation), the undersigned has no way of knowing which documents were disclosed, but would suggest respectfully that there is no basis now to re-designate those documents as AEO.

confidentiality obligations) as part of their respective marketing efforts or when asked to do so.

It appears that ICU is pushing its version of the Protective Order to gain a tactical advantage over RyMed. ICU is Goliath to RyMed's David, and the effect of ICU's proposed Protective Order would be to force RyMed to hire expensive consulting experts to defend the case, which RyMed cannot afford to do. ICU's proposed protective order would prevent all RyMed personnel from doing such fundamental tasks as attending depositions and helping counsel identify the relevant documents.

For these reasons, as discussed more fully below, RyMed respectfully suggests that the language set out in RyMed's version of the proposed Protective Order is more appropriate for this case.

II. DISCUSSION OF DISPUTES

A. WHETHER HIGHLY SENSITIVE DOCUMENTS AND INFORMATION SHOULD BE CLASSIFIED "ATTORNEYS EYES ONLY"

1. ICU's Position:

RyMed both develops and markets its neutral displacement needle-free IV connector, the InVision-Plus. Therefore, RyMed's internal personnel would gain an improper advantage if allowed to view secret technical information regarding ICU's products. For example, RyMed would no doubt desire to have its president and CEO Dana Ryan, the holder of numerous needle-free connector patents, assist counsel in evaluating such documents. However, when Dana Ryan sits down to design around the ICU patents RyMed has already been found to infringe, to design improvements to the InVision-Plus design, or, to develop product tests that take advantage of design differences between the RyMed and ICU products, all such decisions would be informed by his knowledge of ICU trade secrets in the event that the requested order is not entered.

Likewise, if RyMed's marketing manager had access to ICU's lead sheets, confidential

communications with potential customers, or marketing plans and strategies, his decisions regarding which customers to target, what marketing message to emphasize with particular customers, and what marketing campaigns to implement will all be tainted with his knowledge of ICU's confidential sales and marketing information.

RyMed argues above that this case does not call for the production of highly sensitive documents and, therefore, there is no need for an "Attorneys' Eyes Only" category. RyMed's argument proves too much. ICU agrees that the majority of documents relevant in this matter are not AEO material. Consequently, RyMed's claim that the designation of some documents as AEO will hamstring its defense is entirely baseless. However, just because *most* of the documents produced in this case (that is, those that have already been publicly disclosed) would not be designated as "Attorneys Eyes Only" under the protective order, documents revealing future marketing plans, internal marketing strategies, sales leads, private communications with customers or potential customers, non-public design and testing information, and similar highly sensitive matters, are exactly the types of document that the courts readily find protectable by an "Attorneys' Eyes Only" provision.[13]

In cases such as this one between direct competitors, "Attorneys' Eyes Only" protective orders are warranted. As Magistrate Judge Pham of the Western District of Tennessee noted:

> In general, courts utilize "attorneys' eyes only" protective orders when especially sensitive information is at issue or the information is to be provided

[13] Moreover, the fact that most of the documents within the categories listed in ICU's Initial Disclosure would not be highly sensitive does not negate the likelihood that some of the within those categories should be designated AEO. Further, RyMed's discovery requests are in no way limited by the ICU's Initial Disclosure and RyMed's discovery will certainly be broader than only those document that ICU believes, at this early stage of litigation, may support ICU's claims or defenses. Particularly given RyMed's history of knocking off ICU's products and bringing frivolous claims in order to secure otherwise confidential information of ICU, ICU should be granted the protection routinely given in cases such as this involving direct competitors and be able to designate as "Attorneys Eyes Only" any highly sensitive confidential information it must disclose in discovery.

> to a competitor. *See Pepsi-Cola Bottling Co. of Pittsburg, Inc. v. Bottling Group, L.L.C.*, No. 07-2315-JAR, 2008 WL 234326, at *4 (D.Kan. Jan. 28, 2008) (ordering financial information to be designated as "Highly Confidential-Attorneys' Eyes Only" for discovery between competitors); *In re Michael Wilson,* 2007 WL 3268475, at *3 (finding that a standard protective order was sufficient because parties were not direct competitors); *Netquote, Inc. v. Byrd*, No. 07-cv-00630-DME-MEH, 2007 WL 2438947, at *1, 4 (D.Colo. Aug. 23, 2007) (limiting discovery of financial information and customer lists between competitors to "attorney-eyes-only"); *Avocent Redmond Corp. v. Rose Elecs., Inc.,* 242 F.R.D. 574, 576 (W.D.Wash.2007) (ordering "attorneys eyes only" designation for financial and proprietary information produced between competitors); *Gaymar Indus., Inc. v. Cloud Nine, LLC,* No. 1:06 CV 62 TC, 2007 WL 582948, at *3-4 (D.Utah Feb. 20, 2007) (ordering "Confidential-Attorneys' Eyes Only" designation for technical and financial information discovery between competitors); *Visto Corp. v. Seven Networks, Inc.*, 2:03-CV-333-TJW, 2006 WL 3741891, at *6 (E.D.Tex. Dec. 19, 1006) (placing computer source code under "attorneys' eyes only" designation); *Blanchard and Co., Inc. v. Barrick Gold Corp.*, No. 02-3721, 2004 WL 737485, at *2, 15 (E.D. La. April 5, 2004) (applying "Highly Confidential," i.e. "outside experts and attorney's eyes only" designation to confidential and proprietary commercial information produced to a competitor).

Westbrook v. Charlie Sciara & Son Produce Co., Inc., 2008 WL 839745, 4 (W.D.Tenn., 2008).[14] In its meet and confer correspondence (Wagner Decl., Exh. D), RyMed notes that Magistrate Judge Pham declined to grant an AEO protective order; however, that was only upon the finding that the parties were not in fact competitors. *Id.*, at *5.[15]

In its meet and confer correspondence, RyMed incorrectly asserts that its principals must be allowed access to all of ICU's trade secret information because of their "substantial experience in a narrow field that cannot be replaced in the 'open market.'" However, the case upon which RyMed relies is substantially different because the information the defendant sought

[14] *See also Ellipsis, Inc. v. Color Works, Inc*., 2004 WL 3142216, 2 (W.D.Tenn., 2004) (finding the parties to be direct competitors and granting defendant TCW's request for an AEO protective order, to "protect TCW's trade secrets, confidential information, and proprietary information while balancing Ellipsis' need for certain documents").

[15] Likewise, in *MGP Ingredients, Inc. v. Mars, Inc.*, 245 F.R.D.. 497 (D.Kan. 2007), cited by RyMed in its meet and confer correspondence, the court specifically found the parties ***were not direct competitors***. Here, RyMed alleges in its pleadings that the parties are, in fact, direct competitors.

to protect was the entire contents of a computer that the defendant was accused of copying from the plaintiff. The Court found denied the AEO restriction based on the finding that "[i]n order to recognize a particular instance of copying such files, one must have a fairly extensive knowledge of what Frees' computer files contain. Frees' trial counsel are not likely to have such expertise." The Court further noted that "no experts currently have the particularized knowledge of Frees' technology necessary to properly evaluate the Southeast documents." *Frees, Inc. v. McMillian*, 2007 WL 184889, *5 (W.D.La.). Here, however, RyMed has previously retained experts to evaluate ICU's product designs and sales data,[16] and those experts have already been subject to and agreed to the protective order terms at issue.

RyMed's claim that documents should not be marked AEO because it is "under-resourced" and cannot afford to hire consultants fails for several reasons. First, RyMed chose to bring this action. Second, while ICU is admittedly a larger company, RyMed's $8 million in annual sales undermine its claim of poverty and put it in a very different category than what appears to be a sole proprietorship at issue in the *Medtronic* case.[17] Finally, RyMed's argument depends on the assumption that it will not be retaining experts in this matter. Any technical information that is beyond the ability of counsel to understand will require expert testimony for trial. The incremental cost increase of conferring with these same experts for the purpose of deposition preparation or other pretrial matters does not justify opening up ICU's trade secrets to

[16] Wagner Decl., ¶ 10 and Exhs. J and K.

[17] *Medtronic Sofamor Danek, Inc. v. Michelson*, 01-2373-GV, 2002 WL 33003691 (W.D. Tenn. Jan. 30, 2002). Further, the court based its ruling on the following facts not present here: Dr. Michelson and Medtronic were not direct competitors, the technology at issue was invented by Dr. Michelson (the party opposing the AEO designation), Dr. Michelson had been privy to Medtronic's confidential information for eight years under a contractual relationship and had further access as an expert retained by Medtronic, and the action had been filed by Medtronic. Not only do the facts in *Medtronic* differ materially from those in this case, but notwithstanding these facts, the *Medtronic* court did issue an AEO protective order with respect Medtronic's sales and financial information. *Id.*, at *3-*4.

a direct competitor, particularly one with RyMed's history.

RyMed also incorrectly asserts that the protective order would prevent its personnel from attending and reviewing depositions, would constrain the flow of information, and would make litigating the case more difficult. The protective order in fact would not prohibit RyMed's personnel from attending depositions of RyMed's employees or third parties that do not possess ICU's highly confidential information. Nor would it prevent disclosure of other deposition testimony within the framework of the protective order. Furthermore, RyMed was represented by well-regarded law firms in the prior two actions, who did not share the concern that the protective orders with standard AEO provisions would unduly hamper litigation.

RyMed further claims below that it will be disadvantaged by the provision deeming deposition transcripts, unless otherwise designated, as AEO for thirty days. This provision, of course, is to allow the party's whose information is disclosed in the deposition time to determine what portions, if any, of the transcript should be designated "Confidential" or "Confidential – Attorneys Eyes Only." If an upcoming hearing or other event requires a decision made sooner than 30 days, RyMed need only ask and ICU's counsel will of course endeavor to accommodate the request. Further, in the prior cases, it was RyMed, not ICU, that routinely designated the entirety of its own employees' depositions and third party depositions as "Attorneys' Eyes Only," often from the moment the deposition began and nearly always before the conclusion of the deposition.[18] With respect to the upcoming depositions, both Ms. Macklin (who is represented by RyMed's counsel) and Dr. Chernecky, who has co-authored many articles and posters with Ms. Macklin promoting the RyMed product over ICU's products, can and likely will allow RyMed's employees to attend their depositions.

In contrast to RyMed's parade of unfounded horribles, the reality is that these parties

[18] Wagner Decl., ¶ 5.

were able to fully litigate the two prior actions under the same protective order provisions to which RyMed now objects. Issues that arose relating to the protective order were resolved without requiring court intervention and neither party sought to modify the protective orders because they found them to be too cumbersome. In contrast, RyMed's proposal below (to allow only a "Confidential" designation initially and require separate motions to seek AEO protection for individual documents or information as such issues arise) will exponentially increase the cost of discovery, overburden the court with discovery motions, and significantly slow down the discovery process. ICU therefore does not accept this proposal, which is contrary to the established case law and common practice.

2. RyMed's Position:

The Federal Rules of Civil Procedure are "to be construed and administered to secure the just, speedy, and inexpensive determination of every action and proceeding." FRCP 1. What ICU has proposed would result in the exact opposite. While AEO provisions are permitted in certain limited instances, they are discouraged because of the burden they can put on an under-resourced party which needs its in-house personnel to assist counsel with technical issues.[19] ICU cannot bear its burden of demonstrating a "clearly defined and serious injury will result" if the information is protected as confidential without the additional, stringent, restrictions in its

[19] *See, e.g., Medtronic Sofamor Danek, Inc. v. Michelson*, 01-2373-GV, 2002 WL 33003691 (W.D. Tenn. Jan. 30, 2002) ("The impact of prohibiting Dr. Michelson's access to the confidential documents, however, would greatly impair his ability to defend himself in the lawsuit initiated by Medtronic and to pursue his claims for breach of contract and infringement. Without access to Medtronic's documents on devices and methods, Dr. Michelson would be unable to assist his attorneys in determining whether the devices and methods were previously sold to Medtronic or are still the property of Dr. Michelson. This issue is the heart of the lawsuit-a lawsuit instigated by Medtronic. Medtronic cannot prevent Dr. Michelson's access to the information which may prove or disprove his ownership rights in a case where it seeks to have those same ownership rights affirmed.") (emphasis added).

proposed order.[20]

As RyMed has learned from its previous dealings with ICU, the inclusion of an AEO provision in a Protective Order constrains the flow of important information between client and counsel, significantly drives up cost and makes litigating a case all the more difficult. For example, under ICU's proposed Protective Order (and as ICU's counsel has confirmed) party representatives would not be permitted to attend any depositions because of the virtual certainty that AEO material would be shared with deponents.[21] Moreover, counsel would not be permitted to discuss any depositions with their clients and their clients would not be permitted to read any depositions transcripts until 30 days after the transcript is prepared, if at all.[22] Practically speaking, this protocol is unworkable and unduly burdensome.

For example, the parties are scheduled to conduct a mediation in this case on Monday, March 28, 2011. ICU has scheduled the depositions of Denise Macklin (a party) and Cynthia Chernecky (a non-party) on March 23 and 25, respectively. The outcome of these depositions likely may bear on the strengths and weaknesses of each side's case. Under ICU's proposed Protective Order, however, the parties will not have the opportunity to be present at these

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[20] *See Key Components, Inc. v. Edge Electronics, Inc.*, 3:07-CV-224, 2008 WL 4937560 (E.D. Tenn. Nov. 17, 2008) ("While we are sympathetic to Defendants' concern that their trade secrets may used to the advantage of a competitor, we believe, on balance, that Plaintiff should be permitted to pursue its claims and prepare for trial with the experts and consultants it chooses, and we will approve Caldon's proposed protective order. The order we adopt does not permit uncontrolled discovery, since it has safeguards built in to prevent Hastings, Hauser and Estrada from improperly disclosing proprietary information to anyone, including Cameron. Plaintiff's proposed order also distinguishes between information relating to how the AMAG product is designed and operates, trade secrets which will still be protected as Attorney Eyes Only, and a much narrower category of performance-related information, such as testing results. Only the latter cannot be designated as Attorney Eyes Only.") (emphasis added).

[21] Of course, such a provision makes preparing witnesses for deposition very difficult and cumbersome, if not impossible in some instances.

[22] To that end, counsel for RyMed understands that certain depositions in the California Litigation and the Delaware Litigation were designated AEO in their entirety.

depositions and thus consider them when deciding whether or not to settle.[23]

In terms of "abuse," the undersigned counsel for RyMed did not represent RyMed in either the California Litigation or the Delaware Litigation. Undersigned counsel for RyMed understands, however, that both sides made extensive use of the AEO designation in both cases.[24] Moreover, given the breadth and scope of the Protective Orders entered in those cases, the undersigned has no real idea of what was designated AEO by either side. Indeed, ICU has taken the position that undersigned counsel cannot even see any of the deposition transcripts from the prior cases, even for those witnesses who are being deposed again in this case. Obviously, this puts RyMed at a disadvantage, since ICU's counsel in this case has access to all of those depositions. ICU should not be permitted to gain a further tactical advantage through its form of the Protective Order.

For ICU to suggest that RyMed simply hire costly third-party consultants to assist with the litigation is not a satisfactory response. Given ICU's size and annual revenue (approximately $200 million), it is easy for it to make such a suggestion. RyMed's revenues (approximately $8 million), on the other hand, are a fraction of ICU's. Requiring RyMed to retain third party consultants would be costly and burdensome.

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[23] Similarly, the outcome of one deposition likely will lead to the need for other depositions, but counsel cannot discuss that, if at all, for 30 days. This reality will slow the pace of the litigation.

[24] That ICU would complain about the scope of RyMed's production in the California Litigation is ironic in light of the fact that ICU propounded 228 Requests for Production of Documents to RyMed and 114 Request for Production of Documents to Ms. Macklin in the present case. Moreover, it is RyMed's understanding that ICU never challenged the AEO designations made by RyMed's attorneys in the California Litigation. Notwithstanding ICU's previous claims that it was RyMed's counsel who "abused" the AEO provisions in the California Litigation, counsel for ICU now claims that counsel for both sides were able to work our their differences without Court intervention. Apparently, ICU cannot decide which position it likes best – either RyMed and its counsel supposedly abused the AEO provision, or the provision was so benign that the parties were able to work out their differences.

Finally, ICU points out that the Protective Order has a provision that permits each side to challenge the other's designation. Again, this is not an efficient or cost-effective way to deal with the issues that likely will arise. Rather, having to involve the Court in these matters only serves to slow the pace of discovery and drive up cost through the possibility of additional Court involvement.

While RyMed respectfully suggests that the AEO provision is not necessary, as a compromise, it would suggest that if the Court believes that the parties are entitled to discover certain critical information that might be entitled to heightened protection, then the Protective Order should have a provision that would allow the producing party to approach the Court and request more stringent protection, including, but not limited to, AEO, if the party could affirmatively justify the need for such protection. An example of such a provision would be as follows:

> *Notwithstanding anything in this Order to the contrary, nothing herein shall prohibit a party or non-party from filing a motion with the Court showing cause why certain, specific documents or information (including portions of deposition transcripts identified by page and line number) should be designated as "Confidential - Attorneys' Eyes Only" upon an affirmative showing by the movant that the information in question constitutes highly sensitive technical or financial information, trade secrets, strategic plans or business information that the producing party believes in good faith could cause it to suffer substantial competitive harm if publicly known or known by agents or employees of the Parties who would have access under this Order only to documents or information designated "Confidential."*

A provision such as the one above would go a long way toward resolving these issues and would eliminate the possibility of either side over-designating documents or other information.[25]

[25] Given ICU's concession that "the majority of documents relevant in this matter are not AEO material," *see* supra at p. 11, having the parties come before the Court in the rare instances when AEO material is at issue will require minimal Court intervention.

B. WHETHER THE PARTY RECIPIENTS OF CONFIDENTIAL INFORMATION SHOULD BE LIMITED TO TWO INDIVIDUALS AND DISCLOSED TO PRODUCING PARTY

1. ICU's Position:

In the proposed protective order, as well as in the protective orders entered in both the prior actions, the number of party-representatives who may be shown the other party's confidential (but not AEO) information has been limited to two. The more broadly confidential information is disseminated, the more likely it is that the information will be improperly disclosed or used. For example, while allowing RyMed's marketing manager to analyze ICU's non-AEO marketing information is not desirable, it is at least limited; showing this information to all of RyMed's sales people to obtain their input, however, creates significantly greater risk of abuse. There is no practical way to monitor or oversee what the sales people might say or do in the field, armed with ICU's confidential information. Human nature, combined with the opportunity to make a commissionable sale, make it likely that ICU's confidential information would be improperly used to increase RyMed's sales at ICU's expense.

RyMed's argument below ignores the fact that the more broadly confidential information is disseminated, the greater is the likelihood of improper use or disclosure. There are a limited number of decision-makers in any organization who would be able and necessary to render meaningful assistance to counsel in understanding the implications of the opposing competitor's confidential information. RyMed is a medium-sized company, with a single product line, largely run by one individual, Dana Ryan, its founder and principal inventor. RyMed does not explain why it needs to reveal ICU's confidential information to four of its employees rather than the two proposed by ICU. ICU therefore respectfully requests the disclosure remain limited to two employees.

2. RyMed's Position:

RyMed has not proposed that either side be permitted to share Confidential Information with "all of [their respective] sales people." Rather, RyMed has proposed that each side be permitted to share Confidential Information with those individuals who "Trial Counsel believes in good faith have a need to see the Subject Discovery Materials for purposes of prosecuting or defending the litigation." This is not an unreasonable proposal. As officers of the court, counsel for both parties can determine for themselves who needs to see the information in question. Returning to the topic of settlement/case analysis, it is not inconceivable that the flow of information to the client will most likely result in the most realistic evaluation of the case for both sides. Moreover and as noted above, given the claims and defenses at issue in this case, it is difficult to imagine why such a heightened level of protection is necessary.

Although RyMed respectfully suggests that the disclosure be limited to those who counsel believes would assist in the litigation, to the extent the Court would like for there to be a fixed number, RyMed respectfully requests that four people be permitted to see the information in question. Although at this stage of the litigation, it is impossible to tell exactly what will be produced and who counsel will need to consult, having four individuals likely will suffice.

C. WHETHER PRODUCING PARTY SHOULD HAVE AN OPPORTUNITY TO OBJECT PRIOR TO PROTECTED INFORMATION BEING SHOWN TO RETAINED CONSULTANTS

1. ICU's Position:

The proposed protective order would require the advance disclosure of the names and CV of any expert witness to whom the receiving party intended to show the producing party's confidential information and allow for objection to such disclosure.

This provision protects both parties from disclosure of their technical information to third-party competitors or agents of competitors. For example, in the California and Delaware

Actions, RyMed designated Karl Leinsing as an expert to whom it intended to disclose ICU's confidential information. ICU objected to this designation on the grounds that Leinsing prosecuted patents relating to the Alaris SmartSite needle-free connector and appeared to be actively pursuing patents that compete with ICU's CLAVE® patents. Ultimately, RyMed withdrew Leinsing and replaced him with another expert who was not prosecuting patents in the needle-free connector field.[26]

It is equally important to protect the parties' secret design, sales, and marketing information from disclosure to third-party competitors as to each other. This information, in the hands of any competitor, could be used either intentionally or inadvertently to the detriment of the producing party. Given years of work, and millions of dollars invested in research and development, this provision provides reasonable protection to both ICU and RyMed and does not create any undue burden. Further, Rymed's proposal, which would allow the parties to reveal the other's confidential and trade secret information to undisclosed experts, does not adequately protect against disclosure to experts with ties to third party competitors. By the time the expert's name is disclosed with the service of the expert reports, that expert will have already had access to the confidential information potentially for many months. Further, the party designating the expert will likely not have time to retain a different expert to replace the conflicted expert. Under these circumstances, the parties are best protected by requiring them to disclose the names of expert witnesses to whom they intend to provide the other party's protected documents and information.

2. <u>RyMed's Position</u>:

As noted above, undersigned counsel for RyMed is largely unaware of what did or did not take place in either of the Delaware Litigation or the California Litigation. Nevertheless,

[26] Wagner Decl. ¶ 10 and Exhs. L and K.

those events should have no bearing on this case. That being said, if the Court declines to include an AEO provision in the Protective Order, then many of the issues raised by this proposed provision (and the need for it) largely go away.

As a general rule, the identity of consulting experts typically does not have to be shared with opposing counsel. Rather, under Rule 26, typically only testifying experts are disclosed. This provision would turn those concepts upside down and require early disclosure of experts contrary to what the Rules and the Initial Case Management Order provide. For that reason, a more reasonable approach would be for Counsel for each party to retain in their own file a certification by any consulting expert that he or she will abide by the terms of the Protective Order. In the unlikely event of a claimed breach of the terms Protective Order, the certifications could be produced *in camera* or as the Court otherwise directs.

D. WHETHER PERSONS RECEIVING PROTECTED INFORMATION SHOULD BE PRESCRIBED FROM PROSECUTING PATENTS IN THE NEEDLE-FREE CONNECTOR FIELD FOR A PERIOD OF TIME

1. ICU's Position:

The proposed protective order prohibits any person who receives the other party's confidential or AEO information from preparing or prosecuting patents in the needle-free connector field for two years following the termination of the litigation. Disclosure of ICU's secret design information to a third-party who prosecutes patents in the field is just as dangerous and potentially harmful as disclosing that information to RyMed. RyMed admits that this is a highly competitive industry; the protections sought by ICU are reasonable, warranted, and not unduly burdensome.

The conundrum posed by RyMed below is easily solved: RyMed's counsel can consult with its design expert with respect ICU's technical information, just as ICU will consult with its

experts rather than show RyMed's trade secret design documents to those of its employees who are involved in prosecuting patents.

2. RyMed's Position:

RyMed is a small company with approximately 30 employees. By prohibiting the recipient of Confidential Information from preparing or prosecuting patents for two years following the termination of the litigation, the proposed Protective Order would be extremely prejudicial to RyMed and its business. For example, Dana Ryan, the president of RyMed, is an inventor on every RyMed patent. Under ICU's proposal, RyMed and Mr. Ryan (and others) will find themselves in a proverbial Catch-22: (1) disclose the information to someone who is necessary to defend the lawsuit and have that person waive his or her right to prosecute or prepare patents for two years; or, (2) not have that person assist with defense of the lawsuit, but preserve his or her ability to advance RyMed's and/or his own long-term business. These choices should not be mutually exclusive, but under ICU's proposal they are.

Nowhere are the parties being asked to waive their respective rights to file a claim for patent infringement against the other in the event that they believe patents have been infringed. For that reason, in the unlikely event that one side believes that their patents are being infringed, they are more than free to bring suit to address such a claim. Of course, the parties also retain all of their rights to seek enforcement of the Protective Order as well.

E. WHETHER THE PRODUCING PARTY SHOULD BE ENTITLED AS A MATTER OF RIGHT TO DEPOSE THE RECIPIENT OF PROTECTED INFORMATION IN THE EVENT OF A BREACH OF THE PROTECTIVE ORDER

1. ICU's Position:

Just days following ICU's objection to Karl Leinsing as an expert to whom RyMed would disclose ICU's confidential information, RyMed's counsel admitted (as it was required to

do under the protective orders) that it had, in fact, already transmitted ICU's confidential information to Leinsing.[27] As a result of that disclosure, ICU was able to take Leinsing's deposition on the specific subject of the improper disclosure and learn the extent of RyMed's transgression so it could take such protective measures as it felt necessary.

If one party violates the protective order, whether inadvertently or not, and thereby puts the other party's confidential intellectual property at risk, that party should be required to inform the producing party so that the producing party may take what steps it deems necessary to limit the harm caused by the other's breach, which steps may include deposing the recipient to determine the extent of the disclosure and harm caused by the breach.

2. RyMed's Position:

RyMed does not object to the first sentence of Paragraph 19. Rather, RyMed's objects to the concept that no matter what the disclosure, the other side has the right to depose the individuals to whom the information was disclosed. RyMed is confident that in the unlikely event of a breach of the Protective Order, the Court will take whatever steps (e.g. requiring a deposition or some other requirement) it deems necessary to remedy the same without the parties stipulating in advance how that might take place, regardless of the scope of the disclosure.[28]

[27] Wagner Decl., ¶ 9 and Exh. M.

[28] As the undersigned counsel for RyMed did not represent RyMed in the California Litigation, we do not know any of the details regarding the allegations concerning Mr. Leinsing. That being said, it is RyMed's understanding that what is alleged by ICU was simply a mistake by RyMed's counsel without the knowledge of RyMed. In fact, ICU's statement in this document is the first time RyMed became aware that Mr. Leinsing's deposition was taken. All of this, of course, points to how AEO provisions and the over-designation of such material can choke off the flow of important information between counsel and clients.

F. WHETHER COUNSEL FOR THE RECEIVING PARTY SHOULD BE ALLOWED TO RETAIN A COPY OF PROTECTED DOCUMENTS AND INFORMATION AFTER TERMINATION OF THE ACTION

1. ICU's Position:

ICU has consented to certain modifications of the document destruction/retention provision requested by RyMed, including extending the destruction period to 60 days after termination of the action. It should be noted that documents designated "Confidential" or "Confidential – AEO" that are filed with the court are not subject to the destruction provision. As the provision requires destruction of designated documents following termination of the action, all documents would be available for any post-judgment appeals. Once the case has terminated, however, there is no reason for counsel for the competitor to retain the producing parties' confidential documents.

2. RyMed's Position:

Both sides agree that the terms of the Protective Order shall survive termination of the Litigation. Given this fact, counsel for each side should be permitted to retain copies of what has been produced so that they will be in a position to defend themselves or their clients should a claim arise that the Protective Order has been breached. Otherwise, one will be hard pressed to determine if the material in question was actually produced in this litigation.

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Respectfully submitted,

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